UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF WEST VIRGINIA

AstraZeneca AB and
AstraZeneca Pharmaceuticals, LP

Plaintiffs/Counter-Defendants,

vs. CIVIL ACTION NO.

1:18-cv-193

1:19-cv-203

Mylan Pharmaceuticals, Inc.,
and 3M Company, and
Kindeva Drug Delivery, L.P.,

Defendants/Counter-Claimants.

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Proceedings had in the status conference of the above-styled action on, May 13, 2022, before Honorable Irene M. Keeley, District Judge, via Zoom videoconference.

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Proceedings recorded utilizing realtime translation.
Transcript produced by computer-aided transcription.

Friday Afternoon Session,

May 13, 2022, 12:30 p.m.

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THE COURT: Good afternoon. This is Judge Keeley. I understand all the parties are on the line and I just wish to confirm that we have Cindy, our court reporter, with us.

So let me call the case and I'll then ask counsel, beginning with local counsel and lead counsel, to note their appearance, please. This is AstraZeneca AB, et al., versus Mylan, et al. The lead case is 1:18-CV-193. The second case is 1:19-CV-203.

The parties have requested this status conference. It had been my understanding at the last hearing that we would not need another one, but an issue has arisen, and I'm happy to hear from the parties on the issues today, so would counsel, beginning with AstraZeneca's counsel, please note your appearance.

MS. LAW: Thank you, Your Honor. This is Sandra Law as local counsel for AstraZeneca. Also on the line is Gary Rubman, David Berl, Anthony Sheh, and Doug Behrens.

THE COURT: And Ms. Law, do you know who will be leading the argument today on behalf of AstraZeneca?

MS. LAW: I believe primarily Mr. Rubman.

THE COURT: All right. Thank you very much. Good afternoon to all counsel for AstraZeneca.

Counsel for Mylan.

MR. O'BRIEN: Good afternoon, Your Honor. William O'Brien with Steptoe & Johnson, local counsel for defendants. And on the line as well for defendants are Shannon Bloodworth and Dave Anstaett, and they will be addressing the Court on issues presented today.

THE COURT: All right. Thank you. And good afternoon to all counsel for Mylan.

Now, I understand that there are some what I would call courtroom issues, but there's also a legal question that I believe should take priority here today, and that is whether Mylan's fact witness, Stephen Stein, may testify about post-priority date evidence. And, of course, I think from reading the material, AstraZeneca contends that he may be an expert witness in fact witness clothing, so this is an issue that has been raised first by AstraZeneca, so -- as an objection in the pretrial order, so I'll take it up that way and hear from whoever is going to argue it for AstraZeneca. Thank you.

MR. RUBMAN: Thank you, Your Honor. This is Gary Rubman from Covington. Just to clarify one point, I'll be handling this issue, but Tony Sheh from Williams & Connolly will be handling the remaining issues for AstraZeneca.

THE COURT: All right. Thank you.

MR. RUBMAN: You accurately described the issue that

we're raising here. Frankly, we were surprised to see Mylan attempt to introduce a brand-new invalidity theory for the first time this week, and that theory is that Mylan's and 3M's product development process, which started a decade after the priority date of the '247 patent, is relevant to written description and enablement.

This theory is so new that Mylan did not even mention it in its summary of material facts and theories of liability or defense that it included at Exhibit 5D to the pretrial order.

In all of our discussions leading up to this trial, Mylan had consistently described this as a two-witness trial, Drs. Pritchard and Young. Mylan did not say anything about Mr. Stein until they sent their witness list. And we didn't know about this new invalidity theory until we asked why Mr. Stein was on that list.

Now, I think the most straightforward resolution of this, in our mind, at least, is failure to disclose. And so that's what I was going to focus on. Mylan never previously disclosed that it intended to rely on its own product development process to support any of its invalidity arguments.

Now, it could have and should have done that in its invalidity contentions, but it said nothing about this, and those contentions go back to July 2019. Those contentions included Section 112 arguments directed at the '247 patent, but

they never mentioned anything relating to Mylan's product development process, nor did they reference any Mylan internal documents or witnesses who might testify about that.

Second, Mylan's invalidity expert, Dr. Pritchard, did offer opinions on 112 directed to the '247 patent, but just like in the invalidity contentions, he said nothing about Mylan's product development process or its documents, or he didn't even mention any discussions with Mylan witnesses, let alone Mr. Stein.

The other area relating to failure to disclose would be the initial disclosures that, as you know, both sides submit to disclose who they may offer to testify at trial. Mylan never previously disclosed that Mr. Stein would be testifying on invalidity issues. When it served its invalidity disclosures -- I'm sorry, its initial disclosures, Mylan identified eight witnesses, all current or former AstraZeneca employees, who had said it may call to testify on invalidity issues. Mylan did not disclose any Mylan fact witnesses that would be testifying on anything relating to invalidity.

Now, Mylan did disclose Mr. Stein in those initial disclosures, but the subject of his testimony, they used one word, which was technical. Now, even if Mylan had properly disclosed this new theory, Mr. Stein's testimony would still be improper. He never submitted an expert report. He's clearly not an expert, and I don't believe Mylan's proposing him as

such. But he's also not a POSA. He doesn't meet the Court's definition, which the Court -- which both sides basically agree on and the Court adopted.

The other issue is that Mr. Stein's work at 3M took place almost a decade after the priority date of 2003, and he wasn't even involved in the earliest product development efforts at the company. So our view -- and I know there's some discussion of the case law in the pretrial order, and I'm happy to talk about it -- is that this is not the type of evidence that, even if properly disclosed, would fall within the narrow exception of *Amgen* for the type of post-priority date evidence that may be permissible.

It frankly, to us, sounds more like the type of evidence the Federal Circuit and *Amgen* said is not allowed, which is using this type of evidence to eliminate the state of the art. And we don't really understand what their theory is, but that's our best guess, that they want to talk about their efforts, the state of the art, during the time period when they were working to develop their product.

But the final point I'll mention is prejudice. This, in our view, is highly prejudicial to AstraZeneca; brand-new invalidity theory on the eve of trial. Now, with a little bit of irony, you may recall a couple years ago, about two years ago, we sought -- there was an issue about Dr. Berkland's supplemental infringement theory which we served four or five

months before the first trial. That ultimately was not allowed in. But this situation, in our mind, is even worse. There's no expert report here, no advance notice, and literally the eve of trial. For those reasons we ask that you strike Mr. Stein and not allow Mylan to advance this new invalidity theory.

THE COURT: All right. Thank you.

Who's going to argue for Mylan?

MR. ANSTAETT: Good afternoon, Your Honor. This is David Anstaett of Perkins Coie. I will argue on behalf of Mylan.

THE COURT: Okay.

MR. ANSTAETT: Your Honor, Steve Stein is a fact witness, and he is not presenting a brand-new invalidity theory. He's not presenting an invalidity at all. He is a fact witness who was very involved over the course of many years in the development of defendants' accused ANDA products. He's familiar with all the stability testing that was required to ensure that defendants' products are suitable for therapeutic administration to patients, and he will testify about the amount of work it took to develop a single formulation within the broad scope of the asserted '247 patent claims.

And we anticipate that his direct testimony, which will be entirely factual in nature, will take about 30 to 45 minutes. And I do want to stress, when I say entirely factual

in nature, Mr. Stein is not going to offer an opinion about whether the claims are definite or whether they are described adequately or whether they are enabled. He's not going to be doing that because he's not going to be testifying as an expert witness.

So why is this testimony relevant? Well, as the Court knows, the prior patents in this case recited precise grades and concentrations of ingredients, including PVP, which in the prior patents was grade K25, and in a very specific concentration of .001 percent. And as the Court also knows, we don't infringe those claims because defendants' products have a different PVP concentration, so AstraZeneca has now dropped its infringement claims as to those three patents.

The '247 patent, which is the one at issue in the upcoming trial, has immeasurably broader claims than the patents in the first trial. Just as an example, Claim 1, which AstraZeneca is asserting, simply recites a stable quote/unquote formulation, with absolutely no limits on the grade or concentration of PVP and PEG or any form or amount of budesonide and formoterol, so the claims are very broad. And because of that, defendants have stipulated to infringement of the asserted '247 patent claims, but we are defending on Section 112 grounds.

And as the Court knows, when it comes to written description and enablement, a patentee has to show the full

scope of the claims are described and enabled, not just a handful of examples, but the full scope of the claims, and that means that the specification has to show that the skilled artisan knows how to make and use the full scope of the claims without undue experimentation and that the inventors were actually in the possession in the full scope of those claims.

And that's what the Federal Circuit's case law makes abundantly clear is that an accused infringer's efforts to develop a product that falls within the scope of the broad claims is relevant to assessing written description and enablement. And why is that? Because if you have very broad claims and it takes the accused infringer a significant quantity of experimentation to develop a single product, a single embodiment within the scope of those claims, that's relevant to whether the specification shows possession of the full scope of the claims and whether or not the claims require undue experimentation to practice.

And that's what the *Amgen v. Sanofi* case that we cite in the pretrial shell stands for. There you had an accused infringer who sought to introduce fact testimony about its product development efforts to support its written description and enablement defenses, and the District Court excluded that evidence because it was post-priority date evidence and the Federal Circuit reversed and it remanded for a new trial so that that precise evidence could be considered.

And it's entirely appropriate to consider that same kind of evidence in this case. This is not expert testimony. As I said, Mr. Stein is not going to get on the stand and offer an opinion about whether the claims are definite, described, or enabled. He's going to give factual testimony about defendants' product development efforts.

And on that topic, he was deposed not once, but twice, on, again, the very topic that he will be testifying about, defendants' development of the ANDA products. He was quizzed by AstraZeneca on that topic, using more than 70 exhibits, over the course of two depositions, most of them dealing with product development. He was a 30(b)(6) corporate witness for the defendants on multiple topics related to the research and development and stability of the ANDA products.

So AstraZeneca not only had every opportunity to quiz Mr. Stein on the issues he's going to be testifying about; it took those opportunities over the course of two very lengthy depositions.

The notion that I heard my friend on the other side suggest was that the only way this can be relevant is if Dr. Pritchard relied on Mr. Stein's testimony in his expert reports is simply false. They don't cite a single case for that proposition in the pretrial shell. Written description, as Your Honor knows, is a fact question, and enablement is a legal question that's based on a number of underlying factual

findings. And Mr. Stein will be giving factual evidence that the Court can evaluate in assessing defendants' 112 defenses.

We disclosed Mr. Stein, as they concede, in our initial disclosures, as a witness with technical information who defendants may use to support their claims or defenses, and that is precisely how he is being used, as a fact witness with technical information on our product development that is going to be used to support our claims and defenses.

And again, the notion that this is some new invalidity contention is wrong. In our invalidity contentions from the beginning of this case we contended that these claims are so broad that they require -- and the disclosure and the specification so narrow that they require undue experimentation to practice the whole scope of the claims. And that's exactly what this testimony, this factual testimony, is designed to show.

And so I think that the case law is on our side. I think that's what happened in *Amgen* and *Sanofi* was it's exactly what happened here. We want to talk about our product development effort. It was long and laborious and the District Court excluded it and then the whole case had to be remanded to hear that evidence again because the Federal Circuit made clear post-priority date evidence of an accused infringer's product development effort is relevant to these 112 issues.

And again, that's exactly what Mr. Stein was

disclosed as a witness on, the factual description and the facts underlining the development of our product. He's not going to be testifying about the state of the art, illuminating the state of the art at some later time period. He's not going to be testifying about that, so I just feel very strongly that the case law, the disclosures in this case, the fact that he was subjected to dozens of hours of deposition on all the kind of documents he's going to be asked about in a relatively short direct examination at trial, I don't see any basis for striking him.

THE COURT: All right. Thank you.

Did AstraZeneca want to respond?

MR. RUBMAN: I would like to. Thank you, Your Honor.

I'm not going to go through everything. I'm not going to litigate here the 112 issues. There will be plenty of time for that next week.

A few points. Mr. Anstaett referred to the invalidity contentions, but what he didn't refer to was any disclosure in there that they intended to rely on this type of evidence. There is nothing. And I think that's undisputed and that's a really important fact here is when you get down to this, you don't even need to get to *Amgen*. There's a failure to disclose here. There's a last-minute disclosure of a new theory here, and that's at the core of the problem here.

Mr. Anstaett is right that we deposed Mr. Stein.

That deposition was not directed to any 112 issues, because he wasn't disclosed for that. It was really directed to, for the most part, infringement issues. So we haven't had a chance to depose Mr. Stein with an eye toward the 112 issues because we didn't know that he was going to be testifying on anything relating to invalidity.

Amgen -- just to be clear there, *Amgen* did allow some evidence of post-priority date product development efforts, but it was a very different case, and the court was clear that those were limited exceptions. That case involved claimed antibodies and it was an issue about whether or not there was a sufficient number of specific antibodies disclosed, and so there was a lot of back and forth on that; a very different issue than what we face in this case.

At the end of the day, the -- if Mr. Stein were allowed to offer this testimony, someone has to say that this work, this process development efforts by Mylan, was undue experimentation. Dr. Pritchard cannot say that. He did not talk about Mr. Stein. He didn't offer any opinions, so they are ultimately not going to have any expert who's going to be able to refer or offer an opinion based on any of this product development work.

And then I guess the final point I make, and I wrap up because I know there's other issues, Mr. Anstaett obviously made a lot of comments there. All of this -- all of these

facts, all of this testimony, could have been in Dr. Pritchard's report. It could have been disclosed earlier. None of it was. We were surprised, and we don't think it's fair to allow such a late disclosure of a new theory into the case.

THE COURT: All right. Let me ask some questions and I'll start with you, Mr. Rubman.

This '247 patent was certainly not before me in the earlier trial, but all of the discovery to which you're making reference occurred in the lead-up to the earlier case, right?

MR. RUBMAN: That is correct. The '247 patent was in the case back when we were in Delaware, and it stayed in the case when we moved to West Virginia. The initial disclosures that I mentioned and the invalidity contentions were actually back from when the case was in Delaware, so it's been going on for a while. It's been in the case for a while.

THE COURT: All right. Should that be of any interest or concern to me based on the arguments you're making?

MR. RUBMAN: It shouldn't be. I think that supports us, because it's all the more reason why there should have been disclosures years ago, but there weren't. This patent has been in the case, they've offered invalidity and, frankly, 112 arguments with respect to the '247 patent going back to 2019, and so it's been in the case for a long time and they've said nothing on this theory.

THE COURT: All right. Mr. Anstaett, would you like to respond to that issue?

MR. ANSTAETT: I disagree, Your Honor. This is not an invalidity theory. This is factual testimony that goes to the theories of invalidity that have been in this case since day one. And that is -- and the *Amgen* case is not a very different case. The *Amgen* case is on all fours here. The *Amgen*, just like this case, involved very broad claims to antibodies that had certain structural requirements and then a functional requirement, was it effective.

And here we have these very broad structural requirements in the '247 patent claims. Unlike the previous patents, here it's just any PVP, any PEG, at any concentration, with any amount of budesonide or any amount of formoterol, so a very, very broad claim and then a functional requirement, stable. Okay? And that is exactly on all fours with what was going on in the *Amgen* case.

And our position all along has been those claims are so broad and the disclosure in the specification so narrow that you cannot practice the full scope of the claims without undue experimentation. And on written description, it doesn't show possession of the full scope of the claims.

And what Mr. Stein's testimony goes to is not expert testimony. It doesn't require somebody to talk about this in an expert report. There's no suggestion in *Amgen* that that's

what was happening there. It's simply that, as the Court knows, we have a different PVP concentration and we have admitted, because these claims are so broad, we have conceded infringement. We're within the scope of the claims. And then the question becomes if even one embodiment within the scope of these broad claims you had to engage in just an enormous amount of experimentation to get a formulation that was stable and therapeutically effective, that factually is relevant to the *Wands* factors in the enablement inquiry.

So this is not a new invalidity theory. It is evidence that the Court can consider. Obviously, if the Court allows Mr. Stein to testify, you'll hear it and you will evaluate it and weigh it on the factual questions that are written description and the factual analyses that underpin the enablement requirement.

And so our theory has not changed here, that undue experimentation is required, that they haven't shown possession. And as I say, Mr. Stein is going to testify simply about the product development effort that defendants underwent. And as I say, he was deposed ad nauseam on those topics over the course of two depositions, when this case was in West Virginia, in this court, and quizzed about the documents that showed testing for -- can we show this product is stable.

And so I just -- I completely disagree with the notion that this is some kind of new invalidity theory. It's

not. It's factual testimony from a fact witness who was disclosed as such that is relevant to these inquiries.

THE COURT: All right. So if we're looking at the *Amgen* case and we were to analogize this issue to what the question there was, we're talking about post-priority date evidence, and it seems to me that what AstraZeneca's argument focuses on is not that so much as the disclosure question of whether there was a failure to disclose that this evidence was going to be used in order to support the invalidity theories of indefiniteness, written description, and enablement that have been in the case with regard to Section -- or this patent, '247, from the beginning.

Am I wrong about how AstraZeneca has focused its argument, Mr. Rubman?

MR. RUBMAN: Well, you are correct that I focused my argument on the failure to timely disclose this fact evidence as being something that they were going to rely on to support their invalidity theory. That was the focus. The *Amgen*, I did note, is frankly not on point, in our mind. It's a very different type of claim directed at a monoclonal antibody, and we don't agree with Mr. Anstaett's analysis that it's the same case. But you're right that I think the first threshold issue in our minds is, the first time we've heard about this theory in the three plus years we've been litigating it was a couple days ago.

THE COURT: All right. One of the interesting factors, in my experience trying these patent cases, is that there are never any surprises, or at least the parties don't think there should be any surprises or indeed even any curveballs thrown when it comes to the evidentiary issues in the case.

I understand that all trial lawyers have to be facile and they have to be able to adjust to developments as trial occurs, and what I think is happening here is that we're talking about a witness who has been known to AstraZeneca for some time and as we've drawn closer to the trial date next week, there's been drilling down into what actually is Stein going to talk about.

I don't think there's any issue that he's been presented as a POSA. He couldn't be. He doesn't meet the definition, nor do I think that he's in any way, shape, or form a fact witness -- I mean an expert witness, excuse me. He is, in point, a fact witness, and I do think that *Amgen* is somewhat if not wholly on point, since here I don't find that Mr. Stein is being admitted or has testimony that will be admitted on the state of the art on the priority date, which is what a POSA would be talking about. He's going to show that -- or be used to support Mylan's theory of the case under invalidity that the '247 patent is so broad that it does not in its specification disclose the representative -- or didn't fully represent the

aspects of stability that I think are still going to be highly contested here.

Is that essentially -- have I grabbed the essential aspect of your argument, Mr. Anstaett?

MR. ANSTAETT: Yes, you have, Your Honor.

THE COURT: All right. So if we're looking at it that way, Mr. Rubman, I believe this witness should be allowed to testify. This is a trial to the Court. I'm not worried about confusing a jury or misleading a jury. I have the ability, I believe, to weigh this testimony and to determine whether it is within the sphere that I think *Amgen* would allow, or if it veers off into other areas that ought not to come in, particularly when we're talking about the fact that this is not to be offered for what was the state of the art at the time.

I believe that I can make that determination. I'll hear your objections. And candidly, I don't want to fall into the error of not admitting something preemptively that the Federal Circuit may later say should have been admitted during the course of this trial. I can admit this, weigh it, determine whether or not it has any role to play in my evaluation of the three Section 112 issues that I have to evaluate. I would rather do it that way than make the mistake up front and have to try the case a third time.

So we'll go with that ruling of mine today that Mr. Stein can testify on the issues that I understand he's

being offered to support, and we can discuss all of this during trial as necessary, and obviously posttrial as well.

So to the extent that this is an objection in the nature of a motion in limine, I'm overruling the objection to the admissibility of Mr. Stein's testimony and specifically on the issue of failure to disclose, as I stated briefly before, but I'll put it in more detail here. I think this is not a new theory so much as new aspect to theories that have been in the case from the beginning, and to that extent I don't see this as surprising or prejudicial to AstraZeneca.

As I said, we tend to -- in my experience, tend to follow scripts in these trials more than you would see it in other types of cases, and that this may not have been so scripted from the first day the '247 patent was challenged, to me does not mean that it can't be used in this case. Those are my reasons for overruling that.

What I'd like to do now is to move on to the next issue, and why don't we start with how the parties -- will the parties introduce testimony by deposition. I know you don't agree on this, which I find surprising, candidly, but let me hear from AstraZeneca and then from Mylan.

MR. SHEH: Good afternoon, Your Honor. This is Tony Sheh.

THE COURT: You're going to have to speak up, Mr. Sheh. I'm sure the court reporter is having the same

problem I am. You're not nearly so solid and clear as Mr. Rubman was.

MR. SHEH: Understood, Your Honor. That was going to be my first question. Is this any better, Your Honor? Thank you, Your Honor.

So I think based on -- I think Your Honor has asked the question about the manner in which deposition designations will be introduced at the upcoming trial. And by our computation, the plaintiffs have designated about five and a half hours of testimony. And it's about, by my estimate, three hours on the Mylan side, about two and a half hours, so roughly let's call it a 50/50 split there. And that -- I fully suspect the parties will narrow their designations in the coming days, but that will still leave a significant amount of trial time devoted to just playing designations.

And I think the other factor here, Your Honor, is that the parties agree that the testimony from the October 2020 trial is already part of the record and so the Court -- need not be read or otherwise introduced as such into the new trial. And so the Court is essentially receiving a great amount of testimony that has already been recorded in some form, and we feel that the deposition designations coming in the same way places that on the same footing.

And it would just be more -- given this trial has been scheduled for two days, maybe three to accommodate any

potential rebuttal case, but if we -- we like to make an efficient use of Your Honor's time, the Court's time, the parties' time, and the witnesses' time. And given the amount of testimony that is just coming in as -- in written form essentially from October 2020, we think it just makes sense to designate and provide those written submissions to Your Honor.

THE COURT: All right. If I could summarize what I'm hearing. And I'm going to have to ask you to turn off your microphone, Mr. Sheh, because I'm getting the feedback of my own words. Thank you.

You believe that the most efficient way to submit this testimony would be to do it by highlighting -- transcripts that highlight the testimony each side is submitting. Is that it?

MR. SHEH: That's correct, Your Honor.

THE COURT: All right. So and you support that by saying, well, Judge, you're going to have to read through the testimony from the first trial anyway, so here's another couple of hours more reading for you to do. Is that it?

MR. SHEH: I think Your Honor will be guided through the relevant portions of the testimony from October '20 by the parties' agreements, the posttrial briefing, indeed, what the witnesses at the upcoming trial would be -- will be sort of challenged with or used to support their arguments, so I do not think that the Court will need to read the entire October 2020

transcripts, but that October 2020 transcript is very much part of this case.

THE COURT: All right. Without even hearing from Mylan yet on this issue, I just want both sides to understand that this is what I'm talking about when we're talking about scripted trials. I want to see the witnesses. I want to hear from the witnesses, as I'm able to do so, and as it can be done efficiently. After all, I am the finder of fact, correct? So let's go ahead and play these depositions, but I don't think we should break it up. I think if we've got a witness, we should go ahead, play the witness' excerpts, and I should hear this witness as close to real time as I can.

Mylan, I understand, is saying, well, let us play our excerpts in our case, let AstraZeneca play them in its case. I've done that before. I think I'm capable of understanding which side is eliciting which testimony. Why can't we just play these depositions as excerpted straight through? I assume we've got to get rid of all the objections and that I'm not going to have to bear listening to the objections that are no longer relevant at trial?

MS. BLOODWORTH: Your Honor, this is Shannon Bloodworth. I just wanted to say we agree with that wholeheartedly, Your Honor, and frankly, my experience with this has been that as the parties get closer to having to play the videos live, it does get cut down.

For example, we have 12 minutes designated of their inventor, Dr. Marlow, who they're not bringing to this trial. They have 30 minutes, about, so I'm sure that one is going to be quite short at the end of the day, by the time we finish, and we will remove our objections and play for Your Honor each witness in total at one time.

THE COURT: Okay. I want both sides to understand, I don't mind listening to this testimony. It's my job. I'm the finder of fact, as I reiterate. So please, what I do care about is that you do work through these transcripts and eliminate those objections or that argument that -- as it came up during the deposition that I don't need to hear about or rule on. So I hope that is clear to you. Go ahead, play the depositions, and don't break them up so that we're jumping back and forth. Just play them through. And hopefully that will take care of this issue.

I would ask you, Mr. Sheh, do you have any other objection to that ruling?

MR. SHEH: I certainly have no objection, Your Honor. I just want to assure Your Honor that we will be removing objections and colloquies from the -- what is played. The parties agree to that. And, of course, if there are any disputes, they will be raised before the video playing, so I can assure you --

THE COURT: Right. If I have to rule on an objection

based on the video testimony, I'm sure you understand that I will do that. But what I don't want is just these cold page submissions when the witness -- is a video of the witness and I can observe the witness. I think seeing the witness' demeanor can also be very important. Obviously, I'm the fact finder. Okay? Thank you.

MR. SHEH: Understood.

THE COURT: The next question relates to this, and that is to what extent may the parties use evidence introduced during the 2020 trial. And I just heard from AstraZeneca that excerpts will be admitted from the 2020 trial and -- I'm not sure I understand what the dispute is here. Maybe I could hear from Mr. Sheh and then from Ms. Bloodworth.

MR. SHEH: Sure, Your Honor. I'm happy to clear this up. My understanding is that the parties have reached essentially an agreement that the witnesses' testimony from the October 2020 trial is part of the record in this case. We do not currently plan to submit what we call trial designations of that transcript to Your Honor, but we are certainly happy to do that if that would be helpful. But I think the parties will simply just cite to it in their briefing and argument and leave it at that, so I don't think that there's much dispute about what of the October 2020 trial witness testimony is in. I think the parties agree that it's all in.

THE COURT: Well, obviously the testimony that will

be admitted and relied on by me in this case, it will be testimony that is relevant, right, under 401. And maybe not everything from the 2020 trial is relevant to the issues here. I mean, I know it won't all be in there, so I'll rely on all of you to let me know in your briefing, by your citations, what testimony you believe is relevant and admissible, and I'll be sure to look at it, okay?

So if that's the only issue we have there, let's move on to this question of who, if anyone, may be in the same room as the witness testifying remotely. And am I correct that if I drill down to the heartland issue here, one side or the other is afraid that there's going to be an ethical violation and someone's going to be trying to influence the testimony of a witness under oath? I hope that's not what I'm dealing with here, but it sounded like that's what I was dealing with.

MR. SHEH: This is Tony Sheh from Williams & Connolly, Your Honor. I don't think that is where we intend to go on that at all with this. In the October 2020 trial, of course, the witnesses were in a separate room by a sort of default because of the COVID-19 situation. But, as we understand it, there is possibility now that the witnesses will be in the same building as the -- as the examining attorney and their team.

And it is not so much that we believe that there will be any ethical violation; far from it. It is just that in the

remote world we don't have eyes on all parties to observe what's going on. It may not be anything that is intentional, but if there's an issue that crops up, we have no way of knowing that to be the case.

And it also just strikes me that this use of a separate testifying location has been a -- has been a fairly standard practice in sort of remote trial or deposition practice. But I hear Your Honor. So it is not that we think that there's going to be an ethical violation.

THE COURT: Was that Mr. Sheh?

MR. SHEH: Yes, that is, Your Honor.

THE COURT: Thank you.

Ms. Bloodworth, did you want to respond or add anything?

MS. BLOODWORTH: Your Honor, not much. Obviously, we don't anticipate having any unintentional hand gestures or anything to the witnesses. We simply are not sure what our setup is going to look like yet, if our witness and our questioner will be in the same room, or if we'll all be remote.

When this issue came up, we said we're not sure yet. We'll let you know. And we want to let you know we may be in the same building. I think this is much ado about nothing, unfortunately, but we obviously would never do anything unethical, and we assume AstraZeneca's attorneys would not as well.

THE COURT: I would just thank both of you for the assurances and remind everyone that I know you're highly ethical officers of the court and that the case will be presented as it must be, without any attempt to influence the testimony of the witnesses.

Should an issue arise that causes concern to either side, I would be happy to address it at that time, and you can certainly outline for me how your witness will be appearing, where he or she may be located, and if that raises a concern for the other side, I can address it.

Now, may Mylan present a rebuttal case. I know AstraZeneca's position is that no rebuttal case is necessary because there are only two live witnesses for trial, but as I said during our last conference, I believe, if Mylan, who bears the burden in this case, believes it has a rebuttal case, I'm happy to consider letting them put it on once I understand what they want to do.

If I don't think a rebuttal case is appropriate, then they won't get to do it, but up until that point in time, they certainly have the opportunity to introduce rebuttal as it is appropriate under the rules. All right?

So with that issue, I think the only thing left is whether exhibits should be marked up live at trial. And are we talking primarily here about demonstrative exhibits, or is there something that I'm missing?

MR. SHEH: This is Tony Sheh again, Your Honor. It is not -- it wouldn't be demonstratives. The parties agreed -- this is actually a very narrow issue, as I understand it. The parties agree that demonstratives will be exchanged. This is simply markup to already disclosed exhibits; in other words, exhibits that one side has already informed the other that they will be using on direct. These are essentially, go to page 2, column 26, highlight the third paragraph of sentence -- of the -- whatever sentence.

And I believe at the first trial it was permitted to prepare those sort of callouts and mark those versions in advance without exchanging them, because, again, the entire exhibit has been disclosed to the other side, and we're simply trying to follow an efficient practice from the first trial.

THE COURT: Now, before I hear from Ms. Bloodworth, what I'm sure you understand, Mr. Sheh, that most judges, to avoid confusion and controversy, require that demonstratives be exchanged prior to their use. And so if parties are going to use demonstratives at trial, whether in opening statements or through a witness, they need to be marked so that they can be indicated appropriately on the record at trial. If that's what you were saying you were going to do, that's fine with me.

Let me hear from Ms. Bloodworth as to whether there's something I've missed.

MS. BLOODWORTH: Thank you, Your Honor. I think the

concern or at least the confusion is that it sounded to us like plaintiffs wanted to mock up in advance documents, perhaps not in PowerPoint, but in PDF, for example, and alter documents with highlighting and balloons or arrows and not call them demonstratives so they didn't have to exchange them in advance.

In our last trial and in all of my trials before Your Honor, we have always exchanged any preprepared markups, whether it be of a document in PDF or a PowerPoint, so we were operating from that procedure and planning to exchange those documents that were not -- anything that was basically preprepared by counsel for use in front of the Court.

THE COURT: Well, if that's the concern, then let me make it clear, yes, I want those exchanged beforehand in the effort to avoid surprise and controversy as we get this case under way.

Mr. Sheh, is that acceptable to AstraZeneca, or do you have a further objection?

MR. SHEH: I understand Your Honor's position and we have no further objection, Your Honor.

THE COURT: Thank you.

Have I covered all the issues other than to let you know that we're still waiting for TrialGraphix to give us their log-in information. I think you all are the ones who are supposed to let us know that. So when you get it, would you please give it to us as soon as you can?

MR. SHEH: Yes, Your Honor. This is, again, Tony Sheh, and we are working on it. I do want to alert Your Honor to the fact that, as we understand, TrialGraphix is not available due to their own trial schedule, and we are in contact with another remote vendor that will provide the same remote experience that --

THE COURT: I'm sorry, Mr. Sheh, you got garbled there in the last 30 seconds or so, so I missed everything after TrialGraphix is not available due to its own trial schedule.

MR. SHEH: Apologies, Your Honor. Because TrialGraphix is not available, we are in contact with another remote trial vendor that will provide the same Zoom platform that we have used in the past. It's just going to be a different provider. And the parties are working out those minor details and we fully intend to provide Your Honor with the log-in details as soon as we can.

THE COURT: All right. One of the reasons we need that as soon as possible is we have to get it up on our website so those members of the public who wish to view the trial can have that information to log in, of course. Okay? And I assume that this different provider will have the same ability to move the parties into rooms when we have testimony that may need to be under seal because of its nature.

MR. SHEH: That is my understanding, Your Honor, yes.

THE COURT: All right. Good. Thank you very much for that.

Ms. Bloodworth or Mr. Anstaett, anything to follow up on with Mylan?

MS. BLOODWORTH: Nothing further from Mylan. Thank you, Your Honor.

THE COURT: You're welcome.

Mr. Rubman, Mr. Sheh, anything further for AstraZeneca?

MR. BERL: Your Honor, this is David Berl. If I may just raise one further issue relating to scheduling in view of the fact that the depositions are going to be played on videotape and the navigation of the documents will have to happen live rather than beforehand. We just want to make sure that one way or the other that Dr. Young completes his testimony Friday. I don't foresee that being a problem, but as Your Honor may know, he's a foreign witness. He lives in Australia. And we've assured him repeatedly that he will be done Friday, and he's booked and arranged his life and he has to leave after Friday. I just wanted to raise that in the event that it becomes an issue, so if needed some testimony could go out of order in terms of a deposition or otherwise.

THE COURT: Nice hearing from you, Mr. Berl, and I certainly will make every effort to assure that Dr. Young is on and off on Friday. We can begin whenever it works for you all

and for him, and if he has to be taken out of order, I know that Mylan understands that I will allow that based on the scheduling issue that Dr. Young has. All right?

MR. BERL: Thank you, Your Honor.

THE COURT: Keep me apprised and I will -- all of us will pivot as necessary to make sure Dr. Young is not inconvenienced.

Now, anything final before we adjourn?

MR. BERL: No, Your Honor.

THE COURT: All right. If not, I thank you all and wish you a pleasant weekend and pleasant trial preparations, I guess. I'll be with you all next Thursday and Friday unless another issue arises, I assume. And my clerk is looking at me and saying she's sure there will be no other issues, so good luck with that. Thank you.

(Proceedings concluded at 1:21 p.m.)

CERTIFICATE

I, Cindy L. Knecht, Registered Professional Reporter and Official Reporter of the United States District Court for the Northern District of West Virginia, do hereby certify that the foregoing is a true and correct transcript of the proceedings had in the above-styled action on May 13, 2022, as reported by me in stenotypy.

I certify that the transcript fees and format comply with those prescribed by the Court and the Judicial Conference of the United States.

Given under my hand this 16th day of May 2022.

/s/Cindy L. Knecht
_____
Cindy L. Knecht, RMR/CRR
Official reporter, United States
District Court for the Northern
District of West Virginia